

PCN117 USE OF BIOLOGICALLY BASED THERAPIES (BBTs) AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQOL) AMONG MALAYSIAN CANCER PATIENTS

Farooqui M¹, Hassali AA², Knight A³, Akmal A⁴, Farooqui MA⁵, Saleem F⁶, Ul Haq N⁶
¹Universiti Teknologi MARA, Penang, Malaysia, ²Discipline of Social & Administrative Pharmacy, Universiti Sains Malaysia, Pinang, Pulau Pinang, Malaysia, ³Universiti Sains Malaysia, Pulau Pinang, Malaysia, ⁴Universiti Sains Malaysia, Penang, Malaysia, ⁵Alliance University College of Medical Sciences, Penang, Malaysia, ⁶Universiti Sains Malaysia, Penang, P. Penang, Malaysia
OBJECTIVES: To examine the prevalence of Biologically Based Therapies (BBTs) use and assessment of Health Related Quality of Life (HRQoL) in a group of cancer patients. **METHODS:** The study was undertaken with 393 cancer patients at the oncology wards of Penang General Hospital, Malaysia. The health related quality of life was assessed by using European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30). **RESULTS:** Out of 393 participants, 184 (46.1%) reported to use different types of Complementary and Alternative Medicines (CAM). Among the CAM users, 134 (72.8%) reported using BBTs and thus labelled as BBTs users and vice versa. Nutritional supplements such as vitamins, minerals, enzymes (n=139) and special diet such as herbs, animal products, juices (n=74) were the common type of BBTs used by patients. More than half of the participants were not sure of their monthly expenditures on BBTs. However, 26.3% reported to spend an average of 101-500Malaysian Ringgit (MYR) per month on these therapies. Friends and family members were the most common source of BBTs recommendations (75.5%). BBTs use was disclosed to the doctors by 42.1% of the participants. BBTs users reported better HRQoL compare to non BBTs users. On functional scale significant difference was observed in role (p=0.01) and emotional (p=0.04) scores between BBTs users and non-users. On symptoms scale fatigue (p=0.006), nausea & vomiting (p<0.001), pain (p=0.04), insomnia (p=0.01) and appetite loss (p<0.001) were significantly different among BBTs users and non-users. No significant difference was found in Global health status/quality of life score between BBTs users and non-users (p=0.85). **CONCLUSIONS:** The use of biologically based therapies is common among cancer patients in Malaysia. HRQoL assessment reveals better quality of life of BBTs users thus further research is required to evaluate the potential role of BBTs in cancer care.

PCN118 A CRITICAL REVIEW OF EMA LABELING CLAIMS IN ONCOLOGY: 2006-2012

Hao Y¹, Evans C²
¹Janssen Global Market Access, Raritan, NJ, USA, ²Endpoint Outcomes, Boston, MA, USA
OBJECTIVES: To review European Medicine Agency approvals in oncology for 2006-2012 to determine commonly used primary endpoints and endpoints based on patient reported outcomes (PROs). **METHODS:** The initial identification of oncology approvals was conducted in PROLabels (2006-2012). This was supplemented with a review of European Assessment Reports, Summary of Product Characteristics, Procedural Steps, Summary of the European Public Assessment Report and Scientific Discussion documents. **RESULTS:** There were 8 approvals in neoplasms, 3 in anemia, 4 in pain, 1 in nausea and vomiting, 1 in paroxysmal hemoglobinuria. Primary endpoints for approval of oncology drugs included progression free survival (n=5), endpoints based on pain intensity (n=3), overall survival (n=2), hemoglobin stabilization/blood transfusion requirement (n=1), no emesis/no use of rescue medications (n=1), lesion clearance (n=1). PRO measure used included the BPI-SF, MPQ, FACIT-F, FACIT-An, FACT-L, EORTC-QLQ-C30, Pain NRS, nausea VAS, TSQM, Trial Outcomes Index and an unreported measure. The type of PRO endpoints in the approved labeling included: Pain (n=7), HRQOL (n=6), fatigue (n=3), emetic episodes/use of rescue medications (n=1), treatment satisfaction (n=1). **CONCLUSIONS:** Manufacturers frequently supplement primary endpoints with supplemental PRO data. European approvals include labeling information that is often not permitted by the FDA such as improved HRQOL.

PCN119 IMPACT OF CULTURE ON THE QUALITY OF LIFE OF MEXICAN-AMERICAN FAMILY CAREGIVERS OF PATIENTS WITH ADVANCED CANCER

Brannin J¹, Juarez G²
¹University of La Verne, La Verne, CA, USA, ²City of Hope, Duarte, CA, USA
OBJECTIVES: Although Hispanics are the fastest growing ethnic group and cancer the second leading cause of death among Hispanics in the U.S., few studies have documented the impact of cancer diagnosis on the quality of life and caregiving experiences of Hispanic family caregivers. The aim of this study was to explore the influence of culture on the caregiving experiences and perceptions of QOL among Mexican-American (MA) family caregivers of adults with advanced cancer. **METHODS:** This qualitative descriptive study was conducted in the ambulatory care setting of an NCI-Comprehensive cancer care center in the United States. Twenty MA family caregivers of patients with advanced cancer participated in qualitative interviews. Thematic analysis of the interviews and the conceptual model of Quality of Life Well-being developed by Ferrell, Wisdom, and Wenzel (1989) were used to characterize the caregiving experience and the effects of caregiving on QOL of MA cancer family caregivers. **RESULTS:** In general, the caregiving experience and the meaning of QOL centered on spiritual or religious beliefs and practices, concern for providing the best home care, inclusion of extended family support, and the desire to fulfill cultural role and responsibility expectations. Overall, MA caregivers emphasized that their caregiving experience had more positive than negative outcomes. The caregiver's overall QOL was primarily affected by the patient's advanced disease, the consequences of the cancer treatment and its related side effects, and the patient's emotional/psychological needs. Secondarily, the caregiver's overall perception of quality of life was affected by their physical, social, emotional and

spiritual needs. **CONCLUSIONS:** These findings provide insight into the cultural dimension inherent in the caregiving experience and perceptions of QOL of MA cancer family caregivers. It is imperative to recognize the influence of culture in developing culturally relevant interventions specifically designed to reduce the burden of cancer and improve overall caregiver QOL.

PCN120 PATIENT REPORTED OUTCOMES IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: A SYSTEMATIC REVIEW

Aggarwal S, Segal J, Messenger M
 Novel Health Strategies, Bethesda, MD, USA
OBJECTIVES: Patient reported outcomes (PRO) are becoming useful tools for collecting and generating evidence for new medical products to show improvements in health-related quality of life (HRQoL). Castration-Resistant Prostate Cancer (CRPC) is a chronic disease with high importance for patient HRQoL. The objective of this study was to review, analyze, and understand trends in the PRO instruments used in patients with CRPC. **METHODS:** A systematic literature search for CRPC randomized controlled trials (RCTs) with PROs endpoints was undertaken for the databases Pubmed, Embase, Biosis, Google Scholar, and Cochrane. Data was collected for the study size, interventions, year, PRO instrument, and results for PROs. Analysis was conducted to identify trends in commonly used PRO instruments and categorize results as positive, neutral or negative. **RESULTS:** Ten RCTs with a total of 5797 patients were identified. In these studies there were 13 different PROs instruments were identified that were FACT-P, FACT-G, BPI-SF, EQC30, EQPR25, FLIC, SDS, SUF, PDA, IPDA, PROSQOLI, SF-36, and QOLM-P14. The most commonly used instrument were FACT-P (used in 4,297 patients) and EQC-30 (used in 1,091 patients). Six studies reported positive results with improvement in quality of life symptoms (QoL) versus comparator treatments. Four studies reported results with deterioration in (QOL). Three studies reported improvement in pain scores. **CONCLUSIONS:** Patients with CRPC have relatively longer survival and hence QoL is an important consideration for these patients. PRO instruments such as FACT-P and EQC-30 have been commonly used to generate evidence to show which therapies improve patient QoL.

CANCER – Health Care Use & Policy Studies

PCN121 GAPS IN US AND EU PAYER POLICIES LIMIT THERAPEUTIC OPTIONS IN PAIN CONDITIONS

Bache G¹, Miller KL², Stevens CA²
¹PAREXEL Consulting, Uxbridge, UK, ²PAREXEL Consulting, Waltham, MA, USA

OBJECTIVES: Despite a shift towards consideration of pain as a focus of treatment rather than a symptom to be managed, the introduction of new products for pain has been detrimentally affected by reimbursement frameworks that are unlikely to support decisions that favour patient access. This situation exists despite public support for effective pain management, particularly within the palliative care setting. This study aims to identify the mechanisms that limit the available therapeutic options in pain management and to suggest potential alternative approaches to be considered. **METHODS:** The study involved interviews with 30 interviewees in the US, France, Germany and the UK, including national level HTA influencers, medical directors, influencers on hospital formularies and product use, palliative medicine consultants, anaesthesiologists and oncologists. Interviews focused on the challenges of securing a favourable reimbursement status and a commercially viable price in a pain indication, as well as the difference between treatment guidelines and clinical practice. The success (or not) of market access for 4 selected pain products was also assessed based upon a set of criteria set out in the poster. The organisational structures for delivery of pain services were also considered. **RESULTS:** New pain products struggle to secure uptake in both the US and EU. Countries adopting a model that attaches the achievable price level with the level of additional clinical benefit demonstrated (France, Germany) are reluctant to consider favourable assessment versus established cheap products. The absence of life extension and common existence of pain in late stage disease means countries adopting a cost-effectiveness model (UK) are methodologically unsuited to evaluation of such products. US payers are likely to place restrictive prior authorisation requirements on products while cheap options exist. **CONCLUSIONS:** Patient access to new pain therapies is significantly limited by reimbursement policy in the US and EU, including in instances where the product has a recognised clinical benefit.

PCN122 PREVALENCE, DIAGNOSIS & TREATMENT PROTOCOLS FOR BREAST CANCER IN SOUTHERN PUNJAB

Ahmad M¹, Khan MS², Usman Minhas M¹
¹The Islamia University of Bahawalpur, Bahawalpur, Pakistan, ²The Islamia University of Bahawalpur, Punjab-Pakistan, Bahawalpur, Pakistan

OBJECTIVES: To explore the prevalence, diagnosis & treatment protocol of breast cancer in patients treated at Bahawalpur institute of nuclear medicine and oncology (BINO). **METHODS:** A retrospective study was carried out on the data from the treatment records of patients (n=300). Patient age, education status, involved breast, type & stage of disease at diagnosis, socioeconomic status of patients & metastasis in patients as well as the treatment protocols was evaluated. Statistical tools were applied for analysis. **RESULTS:** The mean age of patients was 48±15 & 92% patients were illiterate. Infiltrating ductal carcinoma (IDC) 96% was the most common type of breast cancer found in population and were mostly diagnosed at Grade 3 (69%). Most of the patient had carcinoma of